

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA, et al,)
)
Plaintiffs)
)
-VS-) CA No. 16-11372-PBS
) Pages 1 - 79
JAMES F. ALLEN, et al,)
)
Defendants)

MOTION HEARING

BEFORE THE HONORABLE PATTI B. SARIS
UNITED STATES CHIEF DISTRICT JUDGE

United States District Court
1 Courthouse Way, Courtroom 19
Boston, Massachusetts 02210
May 1, 2018, 10:09 a.m.

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OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 7200
Boston, MA 02210
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A P P E A R A N C E S:

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P R O C E E D I N G S

THE CLERK: Court calls Civil Action 16-11372, United States v. Alere Home, et al. Could counsel please identify themselves.

MR. DeNINNO: Good morning, your Honor. Andrew DeNinno on behalf of the plaintiff relator.

MS. McETTRICK: Good morning, your Honor. Jacquelyn McEttrick on behalf of the plaintiff.

MR. KRAUS: Good morning. Lawrence Kraus for mdINR.

MR. KASSOF: Good morning, your Honor. Andrew Kassof for Alere Home Monitoring.

MR. PEARLSTEIN: Good morning, your Honor. Mark Perlstein for Roche.

MR. GELB: Good morning, your Honor. Richard Gelb for CardioLink.

MS. SHANAHAN: Good morning, your Honor. Sara Shanahan for Patient Home Monitoring.

MS. THORVALDSEN: Good morning, your Honor. Kara Thorvaldsen for US Healthcare Supply and Advanced Cardio Services.

THE COURT: All right, thank you. You may be seated. Have you worked out among yourselves an order?

MR. PEARLSTEIN: Yes, your Honor. So I will be going first on behalf of Roche, and then it will be Alere, mdINR, and then that's number four.

1 MS. SHANAHAN: Patient Home Monitoring, your Honor.

2 MR. GELB: I guess we're going last, your Honor.

3 THE COURT: And so how long do you each need because I
4 need to make sure I have enough time for everybody because I
5 need to give plaintiffs fair time, and you may want a brief
6 rebuttal?

7 MR. PEARLSTEIN: So mine may be longer than some, but
8 I'm going to do it in 20 minutes or less.

9 THE COURT: If you do it by 10:30 -- we just need to
10 script this out -- let's say each one of you gets ten minutes
11 and then you get the remainder of the time, does that make
12 sense from your point of view?

13 MR. DeNINNO: Your Honor, I'm not sure I follow the
14 remainder.

15 THE COURT: So it sounds as if 10:30, we'd be done
16 with the rest by 11:30, and you'd get at least a half an hour.

17 MR. DeNINNO: To respond to all seven of the
18 defendants?

19 THE COURT: Or do you think it makes sense -- that's
20 why I'm asking you -- to get going? Would you rather respond
21 person by person?

22 MR. DeNINNO: I think it might make sense to do it
23 that way, your Honor.

24 THE COURT: My concern about that is, just saying, we
25 may not get through everyone, so that's why I'm trying to in

1 advance. I'm happy to go that way, but let's say 20 and -- I
2 won't have time. I'm hoping we're not going to hear the same
3 thing from each one. How do you want to handle it? Would you
4 prefer to go after each one?

5 MR. DeNINNO: My preference would be to go after each
6 one. I don't think we'll need a full 20 minutes to respond to
7 Roche, and I certainly think that as we progress, that a lot of
8 the same issues will repeat themselves.

9 THE COURT: I do think that they will. All right, so
10 why don't we take Roche first, and then we'll keep going. And
11 there's nothing earth-shatteringly urgent about this. If I
12 don't finish everybody, I'll schedule another time for the
13 remaining two. I have to be out of here by 1:00 o'clock, and I
14 think we should be able to finish it in that time frame.

15 MR. DeNINNO: Thank you, your Honor.

16 MR. PEARLSTEIN: Thank you, your Honor. The theory
17 that's being advanced here by the relator is essentially an
18 attack on Roche's decision to limit the frequency that it will
19 support for its testing service for patients who are on
20 Warfarin. It's simply not actionable, and there really are
21 three core reasons for that, your Honor. One, the patient
22 order form -- and there are different versions, but the
23 earliest one is attached as Exhibit F to the amended
24 complaint -- is clear and transparent, and unlike cases we'll
25 talk about a little bit later, no physician has allegedly been

1 misled by that order form. The choices that it provides are
2 clear.

3 Secondly, federal law unambiguously allows providers
4 to determine what services they will provide, and nothing about
5 the theory advanced here alters or in any way should modify
6 that.

7 And, third, the whole notion of coercion in this case
8 is simply implausible. As the materials that the relator has
9 submitted demonstrate, home testing, the testing that's at
10 issue here, represents a tiny segment of the market for testing
11 services available to Warfarin patients. In that circumstance,
12 where so many other options are available to physicians and
13 their patients, including the relator in this case, the notion
14 that limiting this one narrow segment of the market, limiting
15 it in terms of the services offered is in any way coercive is
16 simply implausible, and saying it does not make it actionable.

17 Let me just sketch out a few background facts. I
18 don't think you're going to hear these from anybody else, your
19 Honor. So Warfarin is an anticoagulant. It is prescribed to
20 inhibit clotting. There are three conditions for which
21 Medicare patients can receive -- well, so testing needs to take
22 place for Warfarin, and the reason for that is, Warfarin is an
23 anticlotting agent, but if there's too much Warfarin, it can
24 result in uncontrolled bleeding. So there's a risk of stroke
25 if it's at too low a level, and there's a risk of uncontrolled

1 bleeding if it's at too high a level.

2 Medicare allows reimbursement for patients who test
3 for three conditions: those with a mechanical heart valve,
4 those with atrial fibrillation, those with deep vein
5 thrombosis. In 2006 FDA issued a black box warning which urged
6 physicians to regularly test patients who are on Warfarin for
7 just this reason; and there are a range of views among
8 physicians about the appropriate testing frequency, when
9 patients are to be regarded as stable, and therefore able to be
10 maintained on a lower frequency.

11 The test settings, your Honor, include home, but, as
12 we said, home testing represents a tiny slice of the market.
13 The 2008 CMS decision that expanded reimbursement says
14 5 percent. The Heneghan article from 2012 cited by relator
15 said that only 1 percent of patients are testing at home. This
16 particular percentage is not especially important. The key is
17 that it is a distinct minority of patients who test at home.
18 Most test in hospitals, in physicians' offices, or special
19 anticoagulation clinics that are set up to provide this kind of
20 testing. And indeed the relator, Mr. Allen, did just that.
21 According to his complaint, he tested at a VA hospital, he
22 tested at his physician's office in Buffalo, and then after he
23 moved to Canandaigua, New York, about 100 miles away, he tested
24 at a local hospital there. So he along with other patients has
25 multiple options available in addition to home testing.

1 Reimbursement for home testing, your Honor, it's sort
2 of an unusual system. If a patient enrolls, the patient will
3 receive a testing meter and strips. There is no charge for the
4 provision of the meter and the strips. Every four tests are
5 grouped together in a billing unit under a code. It's G249.
6 And the notion is that through the reimbursement for the
7 testing, the companies that are providing this service will
8 ultimately recover the cost of the meter and the strips.
9 Medicare recognizes that up to weekly testing can be an
10 appropriate frequency for patients because Medicare authorizes
11 reimbursement for patients at that frequency.

12 As to the relator, Mr. Allen, who is the only
13 patient --

14 THE COURT: Does Medicare ever say it's unnecessary to
15 do it once the Warfarin has been testing appropriately for a
16 period of time?

17 MR. PEARLSTEIN: It doesn't. It simply states once
18 per week, and while I don't think --

19 THE COURT: It doesn't ever say "but it's unnecessary
20 in a lot of patients"?

21 MR. PEARLSTEIN: So that's a determination that
22 physicians make --

23 THE COURT: I understand, but does Medicare have
24 guidelines on point?

25 MR. PEARLSTEIN: It does not. It simply -- what

1 Medicare does is authorize as frequently as once per week. It
2 does not provide any guidance that says "but walk that back if
3 X, Y or Z happens." It leaves it to the physician's judgment.
4 And, again, I think it's fair to say -- and we see it in the
5 studies that have been referenced in the papers, and you even
6 see it in Dr. Riegel's care of Mr. Allen -- physicians have
7 different views about how to manage their patients.

8 THE COURT: There's an argument that one of those
9 studies, the 2012, is misleading, or, more accurately, that
10 there's more recent information that makes that misleading to
11 rely on.

12 MR. PEARLSTEIN: So it's actually the other way
13 around.

14 THE COURT: Is it the other way around? All right.

15 MR. PEARLSTEIN: The 2006 Heneghan study is alleged to
16 have been misleading. The 2012 study which relator points to
17 actually doesn't support that. As we lay out in our brief, it
18 specifically does not say, as they allege, that the earlier
19 study was disclaimed or is to be abandoned. What they said is
20 that the 2012 study supplements, it provides additional
21 information about home monitoring. And the other point is, it
22 wasn't a repudiation of any --

23 THE COURT: Excuse me. That Heneghan study, where is
24 that? Is that on your website?

25 MR. PEARLSTEIN: No. So that's a good question

1 because there is an allusion in the -- several allusions in the
2 complaint to unspecified marketing material that had reference
3 to the Heneghan study.

4 THE COURT: The 2006 one?

5 MR. PEARLSTEIN: The 2006 study, that's correct. But
6 it's not identified as to what that material was, to whom it
7 was circulated, or whether even a single physician was
8 influenced by it, or whether even one claim resulted from, you
9 know, the unknown physician having been so influenced, and
10 there's just not much information about it.

11 THE COURT: Well, is it on your website?

12 MR. PEARLSTEIN: I don't know the answer to that.

13 THE COURT: All right.

14 MR. PEARLSTEIN: So --

15 THE COURT: It's not alleged that it's on your
16 website?

17 MR. PEARLSTEIN: It's not alleged as such, that's
18 right.

19 So Mr. Allen began testing with Roche in March, 2014,
20 and it's a fairly simple story.

21 THE COURT: I actually -- just to make sure we move a
22 little more quickly, I read all of this, so I understand the
23 situation with Mr. Allen and Roche and the doctor.

24 MR. PEARLSTEIN: Okay, all right, so then let me hit
25 the legal argument.

1 THE COURT: Yes.

2 MR. PEARLSTEIN: So the physician order form, your
3 Honor, unlike the order forms in other of the cases that have
4 been cited to you, is absolutely clear and transparent. This
5 is not an instance where physicians were deceived into ordering
6 tests that they had not intended to order. It provided a clear
7 frequency. And in fact the only physician who is referenced in
8 the complaint, or the only physicians are physicians who
9 treated Mr. Allen, do not claim to have been misled by the
10 choices. The choices that Roche provided were once a week,
11 twice a month, or two to four times a month. There's no
12 ambiguity about that and no claim that they were at all
13 deceived. There's no --

14 THE COURT: So is there a place to put in once a
15 month?

16 MR. PEARLSTEIN: So there used to be because Roche did
17 support once a month prior to this time. And in July, 2014,
18 Dr. Riegel attempted to change the order. He said, "I had
19 ordered two to four a month, and now I think once a month is
20 appropriate," and Roche responded to that by saying, "We don't
21 support that."

22 THE COURT: Well, where did he write that? I mean, is
23 there a place on the form to say "other" or --

24 MR. PEARLSTEIN: There was a place on the form for
25 "other," and Roche, having changed its policy to no longer

1 support once a month, eliminated the "other" option. But he
2 tried it. Roche said "no," and Roche gave Mr. Allen until the
3 end of September, 2014, to find other testing. And there's no
4 allegation that any of the tests that were provided by Roche
5 were medically unnecessary. They were all pursuant to the
6 order form signed by Dr. Riegel.

7 Now, what relator says is -- and you see this in the
8 affidavit of Dr. Riegel -- that he felt pressured, that he
9 wanted this as an option for at least certain of his patients,
10 and that's why he signed an order form saying two to four times
11 a month. The problem with that from a False Claims Act
12 perspective is that Roche was absolutely entitled to rely upon
13 the physician's order, and the only reason that Roche would not
14 have been entitled to rely upon that order is if it had
15 information that contradicted the order, that indicated that in
16 fact it wasn't --

17 THE COURT: Or there was something misleading on the
18 form.

19 MR. PEARLSTEIN: Well, so if there's something
20 misleading on the form; but if you look at the other examples,
21 the second *Boston Heart* decision that Judge Walton decided in
22 December, 2017, the *Berkeley Health* case, even the OIG guidance
23 makes it clear that the lab that's conducting the test isn't in
24 a position to assess medical necessity.

25 THE COURT: You know, I read that opinion. I thought

1 it was really helpful, except then there's the final tag,
2 "unless there's something misleading that was provided to the
3 doctor," and I agree with both of those statements.

4 MR. PEARLSTEIN: I agree with those statements too.

5 THE COURT: So you can rely on a doctor's prescription
6 or order --

7 MR. PEARLSTEIN: That's right.

8 THE COURT: -- unless the doctor was improperly
9 induced by either false statements or a kickback or some such.

10 MR. PEARLSTEIN: That's right, but that's not this
11 case, and there's no evidence of that.

12 THE COURT: Well, there is some allegations on some of
13 the other forms that there was something misleading.

14 MR. PEARLSTEIN: But not that Dr. Riegel was misled,
15 and he's the single physician in this case. There's no
16 evidence whatsoever that he was misled. And in fact, to come
17 back to the *Boston Heart* case, Mr. Allen tried to fit himself
18 into the construct that Judge Walton ultimately described when
19 he contacted Roche and said, "I'm willing to test twice a month
20 even though it's not medically necessary." So in that
21 circumstance, you have a prescription for twice a month and
22 evidence that it's not medically necessary. And Roche's
23 response was, "No, we are not going to do that." So Roche was
24 entitled to rely upon it. There was simply no falsity here
25 because every claim was medically necessary, your Honor.

1 The lab cases that have been cited to you are each
2 readily distinguishable. We talked about *Boston Heart*. In the
3 *Bane* case, the test form itself was misleading. It wasn't
4 clear, it wasn't transparent, and it deceived doctors, at least
5 at the 12(b)(6) stage. *Family Medical Centers* was a bundling
6 together of medically unnecessary/necessary tests and standing
7 orders that required tests, even if there was no actual
8 physician order. The *Downy* case, the same thing about
9 bundling, and physicians were allegedly misled into believing
10 that these two combined tests both needed to be performed at
11 the same time.

12 The key here is, it's just as you said: It's either
13 that the physician's judgment was corrupted through a kickback
14 or improper inducement, or the physician was deceived or
15 misled. There's no allegations of that in this case.

16 Now, the relator claims doctors were coerced by this
17 choice, and I touched on this earlier. It is implausible.
18 It's not as if home testing represents a majority of the market
19 or is the sole option. Indeed, it is the smallest of the
20 options, and, as Mr. Allen's experience demonstrates, he was
21 able to test in other settings notwithstanding the Roche
22 policy.

23 THE COURT: Well, it does put doctors in a bind,
24 though, because suppose you have someone who's highly frail or
25 elderly or lives a really far distance away and doesn't

1 otherwise have a ride, it puts the doctor in the catch-22. He
2 orders four tests, or he assumes that the person is actually
3 not going to get tested once a month.

4 MR. PEARLSTEIN: So there's two answers --

5 THE COURT: I mean, maybe it's just a horrible
6 conundrum. That's different from a False Claims Act violation,
7 but it does put pressure on the doctor.

8 MR. PEARLSTEIN: So I guess three responses to that:
9 One, it's not a False Claims Act violation. Two, the fact that
10 a patient is elderly and frail in a lot of instances means that
11 they're not well suited to conduct the home testing at all.
12 And, three, the physician's obligation to determine medical
13 necessity is not changed by that. He or she still needs to
14 make a good-faith judgment about what is required for the
15 patient.

16 THE COURT: So you're saying that the -- I understand
17 exactly what Dr. Riegel was saying. I mean, the doctor feels
18 some pressure that for someone who doesn't have ready access to
19 a clinic, the choice may not be between four and one; it may be
20 between four and none.

21 MR. PEARLSTEIN: But that's not even our case because
22 to take this example, and it's the only example we have in
23 front of us, Mr. Allen moved 90 to 100 miles away from
24 Dr. Riegel's clinic in Buffalo, but we know from Mr. Allen's
25 affidavit that he tested in his new hometown, Canandaigua, at

1 the local hospital. So it is ultimately about convenience,
2 patient convenience, nothing more than that, and it's not
3 actionable under the False Claims Act.

4 THE COURT: Well, it may be more than that. I mean,
5 maybe not just convenience; it's the ability. But, anyway,
6 that may not be a False Claims Act problem. So we need to
7 finish this up.

8 MR. PEARLSTEIN: All right, so let me just hit on two
9 other points. One --

10 THE COURT: Quickly, because then I need to get them,
11 and we have so many people who want their day.

12 MR. PEARLSTEIN: So providers do not have an
13 obligation to provide any service that a doctor deems medically
14 necessary. That's their contention. Federal law is to the
15 contrary.

16 THE COURT: Yes, I understand that. Okay.

17 MR. PEARLSTEIN: Okay. And then I've touched on the
18 false statement piece already.

19 THE COURT: Yes, because I'm going to ask them about
20 that because that is one of the ways of inducement is by -- I
21 mean, I had that in my *Neurontin* case where there was false and
22 I would say even fraudulent information being marketed directly
23 to the doctors, and that is one of the exceptions to this. So
24 I'm going to find out exactly what you're alleging with respect
25 to Roche.

1 MR. DeNINNO: Your Honor, I am going to get into just
2 briefly our theory of the case. I would like to respond to --

3 THE COURT: That's fair, because that could be like an
4 umbrella for all of them. Fair enough.

5 MR. DeNINNO: I would like to respond to at least one
6 of the specific contentions made by Roche, which is that
7 coercion is implausible as alleged by the amended complaint.
8 In fact the amended complaint, as you know, includes an
9 affidavit from Dr. Riegel. And Dr. Riegel specifically
10 reported that in or about 2013, representatives called the
11 Buffalo Cardiology and Pulmonary Associates Coumadin Clinic to
12 inform them that all of the patients of the Coumadin Clinic
13 would have to start agreeing to test -- or the physicians would
14 have to agree that the patients would have to test at least
15 every two weeks, or else they would not be allowed to continue
16 participation in the Roche program.

17 What Roche didn't say is that "We're no longer going
18 to provide services to the patients who are testing monthly."
19 They told the doctors that "You have to switch the patients
20 over to testing every two weeks." So this isn't a situation
21 where Roche decided to stop offering services to patients who
22 required monthly testing. Instead, Roche called the physicians
23 and attempted to make them change all of the patients over.
24 And in Mr. Allen's specific case, Roche was aware that Buffalo
25 Cardiology had previously ordered INR testing pursuant to the

1 independent physician judgment, which we also explain in the
2 complaint and in Dr. Riegel's affidavit is based on an
3 algorithm physicians at Buffalo Cardiology developed. That
4 algorithm required testing to be performed based on the
5 previous result, so --

6 THE COURT: At the end of the day, the problem I have
7 with this is, Dr. Riegel didn't sign off, and they stopped. So
8 there's that -- you wrote 50 pages on this topic, but pretty
9 much I've got to have a false claim. You know, I get it
10 that -- I don't have any false claim with respect to Roche.

11 MR. DeNINNO: Well, the initial prescription that
12 Roche had Dr. Riegel sign, which was because of the limited
13 options for two to four tests per month, when Roche was aware
14 that Dr. Riegel would have prescribed testing pursuant to the
15 algorithm, that led to actual submissions by Roche before the
16 dispute arose about whether or not Mr. Allen, when he received
17 the letter from Roche telling him that he had missed a test and
18 that's what led to this whole --

19 THE COURT: There were no false claims put in, right?

20 MR. DeNINNO: Your Honor, we allege that there are
21 because Roche --

22 THE COURT: So you're talking about the one false
23 claim before they stopped?

24 MR. DeNINNO: That was the only actual claim that
25 Roche knew, but that also leads me into the theory of the case

1 overall, which is that every time the defendants, including
2 Roche, had a doctor sign one of these enrollment forms, and
3 really even before they signed the enrollment form, by
4 instituting this policy where they determine the test
5 frequency, they necessarily violated regulations that were
6 express conditions of payment. The home INR testing is covered
7 by Medicare pursuant to a national coverage determination.
8 That national coverage determination specifically says that
9 every test must comply with -- it's 42 CFR 410.32(a), which
10 says that tests not ordered by the physician who's treating the
11 beneficiary are not reasonable and necessary. They're also
12 bound by --

13 THE COURT: But the physician ordered it, or at least
14 when he didn't order it, they stopped, and when they do order
15 it, they go. And that Reggie Walton case -- I don't know if
16 you know what I'm talking about -- where he reconsidered --

17 MR. DeNINNO: The *Boston Heart*.

18 THE COURT: Yes, *Boston Heart*, I should call it that.
19 I know Judge Walton. But basically the *Boston Heart* case says,
20 if the doctor orders it, unless the doctor is improperly
21 induced, that's the end of the story.

22 MR. DeNINNO: Well, I think that case is particularly
23 on point with respect to Roche, at least as it relates to
24 Mr. Allen and other patients of the Buffalo Cardiology Clinic
25 because they contacted them and told them that they had to

1 switch their patients over.

2 THE COURT: And they didn't do it. At least there's
3 no proof that they did it.

4 MR. DeNINNO: Well, they did it with respect to
5 Mr. Allen because Mr. Allen when he called in April of 2014 to
6 report what his test result was, Buffalo Cardiology told him
7 test again in a month, which was pursuant to their algorithm
8 because he had had several tests --

9 THE COURT: Right, but then there were no claims put
10 in.

11 MR. DeNINNO: Right, but all of the tests that were
12 performed previous to that were based on Roche's improper
13 mandate, and Dr. Riegel never signed an order based on his own
14 independent physician judgment.

15 THE COURT: So just maybe I don't understand the
16 chronology well enough. So Allen gets tested once a week,
17 right? And then he says, "I don't need it once a week." And
18 the doctor says, "He doesn't need it once a week," and then
19 they stopped. Do I have this --

20 MR. DeNINNO: After Allen contacted Roche and he then,
21 you know, realized that Roche was asking him to test in a
22 manner that Dr. Riegel had not intended or that Dr. Riegel
23 didn't believe was necessary, or wasn't pursuant to
24 Dr. Riegel's independent physician judgment, then Roche
25 informed him that they would no longer allow him to test.

1 THE COURT: Right, so they didn't submit false claims.

2 MR. DeNINNO: Your Honor, we still contend that the
3 claim that they submitted, even --

4 THE COURT: Which claim, the first one?

5 MR. DeNINNO: Yes.

6 THE COURT: The very first one?

7 MR. DeNINNO: Yes.

8 THE COURT: Well, then the first one, you're entitled
9 to at least one test. I mean, I --

10 MR. DeNINNO: Well, they have to perform four tests
11 before they submit a claim, so each claim is the result of four
12 tests.

13 THE COURT: So this case is about three claims? You
14 could settle it tonight, even trebled. I mean, it's just --

15 MR. DeNINNO: I mean, it gets back to my point, your
16 Honor, which is that it's the underlying policy that they
17 admittedly applied to every single patient, and, you know, the
18 falsity is their failure to comply with the regulations. And,
19 as I was saying, the very next regulation beyond the one that's
20 specifically incorporated in the coverage determination is the
21 regulation that applies to independent diagnostic testing
22 facilities, which is what Roche is; and that regulation says
23 that all procedures performed by the IDTF must be specifically
24 ordered in writing by the physician. And this theory that if
25 they limit the options that physicians have and that is a valid

1 physician order, it reads out the entire -- you know, it reads
2 out the word "specifically" from the regulation entirely, and
3 the regulation --

4 THE COURT: Why? Why if it's ordered by a physician
5 as medically necessary and the physician isn't wrongfully
6 induced? I get the --

7 MR. DeNINNO: The physician has to be able to exercise
8 independent judgment.

9 THE COURT: But they don't have to provide a service,
10 right? I can't force them to provide a service that --

11 MR. DeNINNO: No, I think they do have to provide a
12 service.

13 THE COURT: I see. So it's an affirmative obligation
14 to provide it once a month, if so desired by a doctor, even if
15 it doesn't cover their costs? I'd be going a long way, wouldn't
16 I?

17 MR. DeNINNO: Not to provide it once a month, your
18 Honor. To provide it in accordance with physician
19 prescriptions.

20 THE COURT: Well, fine, provide it once a month as
21 prescribed by a doctor, even if it loses money.

22 MR. DeNINNO: Right. But, your Honor, they wouldn't
23 be prevented in that situation, even assuming that they're
24 losing money at once a month, which I'm not sure there's any
25 reason to make that assumption based on the --

1 THE COURT: He alleges it. I don't know.

2 MR. DeNINNO: That being said, they can contact
3 doctors, they can contact patients, they can use truthful
4 marketing to attempt to increase the amount of their sales.

5 THE COURT: So when you say -- and that was the one
6 piece that I did want to ask you about -- untruthful marketing,
7 that is one of the exceptions to this rule. So what are you
8 referring to?

9 MR. DeNINNO: The complaint uses as an example that
10 Heneghan article. The complaint alleges that there were
11 multiple citations to outdated articles, and then --

12 THE COURT: Where? Where? That's what I'm trying to
13 understand.

14 MR. DeNINNO: The complaint alleges that they're in
15 the defendant's marketing materials. The allegations --

16 THE COURT: Roche's marketing materials?

17 MR. DeNINNO: As to Roche, the allegations are on
18 their website, which the complaint refers to marketing --
19 sorry?

20 THE COURT: The allegation is that it's on Roche's
21 website?

22 MR. DeNINNO: The allegation of the complaint is that
23 it's in the marketing materials. The reality is that it's on
24 their website.

25 And with respect to, your Honor, that Heneghan article

1 that Roche cited --

2 THE COURT: And you're saying on the website is the
3 2006, not the 2012, or is it both of them?

4 MR. DeNINNO: There is only reference to the 2006
5 article.

6 THE COURT: Now as we sit here? Or are you
7 referring -- anyway --

8 MR. DeNINNO: As of the time we filed the complaint.
9 I am not sure about currently, your Honor. I can't say that.
10 But the 2012 article --

11 THE COURT: Can I just say, you know, everyone is a
12 product of their experience. I'm no different. So when I had
13 the *Neurontin* case, what was happening is, Pfizer was going
14 door to door with salesmen handing them false information, and
15 there were big conventions paid for at which there were
16 presentations with false information to physicians, and there
17 were false consultancy agreements with physicians. So I had an
18 extreme case, I grant you, but you have to connect the -- I've
19 studied this area of law -- somehow connect the false marketing
20 materials to the physician decision, and at least on here I
21 think what you're saying is, it was on the website? Is that
22 the closest you get to the physician?

23 MR. DeNINNO: Well, we also -- I mean, we have contact
24 from Roche to the Buffalo Cardiology Clinic, both to tell
25 patients to switch over, and later, after the dispute arose of

1 Mr. Allen, to try to mediate the dispute, for lack of a better
2 word, through the clinic.

3 THE COURT: Okay, thank you.

4 MR. DeNINNO: With respect, though -- let me just add,
5 with respect to that 2012 article, it appears that Roche and I
6 think maybe several of the other defendants take issue with the
7 word "disclaimed." The actual article, the language of it were
8 that "The 2006 conclusions were limited by methodological
9 problems and inadequate reporting of important outcome data."
10 The defendants used the 2006 article because it claims that
11 there were reductions in incidences of stroke and hemorrhage
12 and the other adverse outcomes that can happen if the Warfarin
13 is not monitored correctly. The conclusions that were limited
14 by methodological problems in the 2012 study were those adverse
15 outcomes. They specifically found in the 2012 study that there
16 was no statistically significant reduction in the adverse
17 outcomes, except with regard to stroke in certain patient
18 populations, but overall they said that after reviewing the
19 data again, this isn't exactly what happened. So I take issue
20 with the fact that the citation to the 2006 article to the
21 exclusion of the 2012 article is a valid statement by omission.

22 THE COURT: Okay, thank you. All right, so is that it
23 with Roche?

24 MR. DeNINNO: One second, your Honor.

25 The only other thing that I would say with regard to

1 Roche is that this idea that they're entitled to rely on a
2 physician order form that they have limited the choices of the
3 physician, or they know that they're not giving the physician
4 the opportunity to make an independent medical determination, I
5 think means that that order form can't be a valid order. These
6 regulations would have no meaning if it wasn't assumed that the
7 doctors will be making independent medical determinations. And
8 the 410.33(d) specifically prohibits IDTFs from ordering tests
9 based on their internal protocols, which is exactly what's
10 happening here. They're getting doctors to sign these orders
11 because the doctors, as Dr. Riegel explained, didn't have any
12 other choice with regard to some of their patients. And in
13 Mr. Allen's case, it was because he lived far away, but your
14 Honor brought up another valid point, which is that patients
15 can live right next door. If they're wheelchair-bound and they
16 don't have the assistance to get them to the clinic to do the
17 tests, then home monitoring is necessary; and in Mr. Allen's
18 case, Dr. Riegel made a decision that it was medically
19 necessary.

20 THE COURT: Okay, thank you.

21 MR. DeNINNO: Thank you, your Honor.

22 THE COURT: Who's next?

23 MR. KASSOF: I am, your Honor, Andrew Kassof. I
24 actually put together some slides that might --

25 THE COURT: Well, have you shown it to them?

1 MR. KASSOF: I'm going to show it to them right now.

2 THE COURT: That's always a little unfair. You've
3 been sitting here this morning.

4 MR. KASSOF: Well, and in fact I'm only going to use
5 some, your Honor, because I think some of it was covered. I'm
6 going to do my best not to repeat anything that was said
7 previously. May I approach, your Honor?

8 THE COURT: Yes, but just know, if this case proceeds,
9 I don't understand why you didn't show it to them first thing
10 this morning. This comes up all the time, and I think it's --
11 the last case I had, I ended up having to delay it for half an
12 hour for counsel to even be able to read it.

13 MR. DeNINNO: Your Honor, we'll make an objection for
14 the record to not having an opportunity to read this beforehand.

15 THE COURT: Well, do you want to wait? In other
16 words, I don't want it if there's something brand-new in there.

17 MR. KASSOF: There's nothing brand-new, but --

18 THE COURT: Let me put it this way. This is how I
19 handled the last one: If there's something you've not seen
20 before, a document or an argument, you pop up and say, "I move
21 to strike," and I will strike it.

22 MR. KASSOF: Thank you, your Honor. Understood. My
23 apologies.

24 THE COURT: No, I understand, but you wouldn't like
25 someone to do it to you, right? I mean, just it's sort of like

1 the Golden Rule: If you don't want someone to do it to you,
2 don't do it to someone else. You'd probably be very upset if
3 they came in with a stack against Alere that you didn't have
4 time to think about.

5 MR. KASSOF: Well, my only response is, typically I
6 would have done this last night. I take what your Honor is
7 saying, and I'll definitely --

8 THE COURT: Okay, fine. Yes, it happens all the time.
9 It's become my new pet peeve when I'm on panels, so --

10 MR. KASSOF: Well taken, your Honor.

11 THE COURT: All right.

12 MR. KASSOF: The experience Mr. Allen had with Alere
13 is a little bit different than with Roche, but the false claims
14 are no more viable, and that's where I'm going to focus
15 entirely on the allegations and experiences with Alere and try
16 not to repeat at all the prior arguments, to the extent I can.

17 There are four key undisputed allegations, undisputed
18 facts, because they're supported in the complaint with an
19 affidavit by Dr. Riegel and by Mr. Allen, and that is that
20 Mr. Allen had and used other testing options. Counsel for
21 Roche went through those a lot. I'm just going to focus
22 towards the tail end right before Mr. Allen went to Alere.

23 Mr. Allen knew Alere's requirements in advance and
24 asked his doctor to enroll him anyway into the Alere program.
25 Mr. Allen's doctor certified to the medical necessity of two to

1 four times per week in an enrollment form submitted to Alere,
2 and then Alere followed Dr. Riegel's prescription.

3 Your Honor, on Slide 2 I walk through a timeline. All
4 of this is taken straight from the complaint and the
5 affidavits. It's been hit extensively previously, so I don't
6 need to walk through it all.

7 Once Mr. Allen moved to Canandaigua, he had already
8 had experience testing at a hospital, a VA hospital, and at
9 Dr. Riegel's clinic. During that period of time, Mr. Allen
10 alleges that at times the amount of testing frequency had to
11 change because he changed to a vegetarian diet for one period
12 of time, and his medication was changed for another period of
13 time, and he tested more frequently. Then he became, he said,
14 more stable. He moved to Canandaigua, and he wanted at-home
15 testing with Roche.

16 I think the contrast between what happened with Roche
17 and Alere further explains why we don't believe this is a False
18 Claims Act case, and I'll get into that in a second, but what's
19 pretty important from our perspective, your Honor, is that just
20 before Mr. Allen tested at Alere, he was testing at the
21 F.F. Thompson Hospital, which was five and a half miles from
22 his home. And on Slide 3, this is how he reached out to Alere.
23 On January 7 -- this is Exhibit K to the Allen affidavit --
24 Mr. Allen wrote to Alere, and he explained that he just had
25 moved from Buffalo to Canandaigua, so he's now 100 miles from

1 the old clinic that he attended with his doctor. And he said
2 that it was very difficult to make that trip, so he was now
3 testing at the F.F. Thompson Hospital here in Canandaigua.
4 "They do not do the finger stick, so I have to give blood from
5 my arm. We need help in getting into a home testing program."

6 And that, to me, explains why Mr. Allen wanted to
7 choose. It's not because it was a matter of convenience. He
8 preferred the home finger stick method. When they're testing
9 at home, your Honor, they prick the finger, and they put it on
10 a strip and it goes into the meter, as opposed to at the
11 hospital where the blood is drawn intravenously. Mr. Allen
12 explained to Alere that he didn't like having the blood drawn
13 intravenously, he preferred the finger stick, so he wanted to
14 get into a home testing program. That was the reason he told
15 Alere.

16 Alere wrote back two days later -- this is Exhibit L
17 to the Allen affidavit -- and said that "Our program requires
18 that you test at least two times a month. Although some
19 physicians do require home testers to test weekly, that will be
20 up to your physician." So they laid out their program, and
21 three weeks later on Slide 5 is the physician form that
22 Dr. Riegel submitted to Alere, and on this form it gave the two
23 options as to Allen's program. They had a weekly option and a
24 two- to four-month option, and he checked the two- to
25 four-month option by hand. And it said clearly on it that "To

1 remain on service with Alere, patients must test and report a
2 minimum of two times each month," and he certified to the
3 medical necessity of that test. And what the form says is
4 that -- and Dr. Riegel signed it. Even the form says that
5 Alere would not accept stamped signatures. It required the
6 doctor to physically sign the form that was submitted, and it's
7 certified. It says, "I certify that it is medically necessary
8 for the patient to self-test frequently in order to maintain a
9 stable INR, optimize its therapeutic effects, and avoid the
10 complications identified on Warfarin's product labeling. I
11 further certify that the patient's medical record contains
12 supporting documentation to substantiate this medical need."
13 So that was what was submitted to Alere, and I concur with the
14 points earlier that Alere is legally entitled to rely on that
15 signed certification by the doctor.

16 So then --

17 THE COURT: Why won't Alere do it once a month?

18 MR. KASSOF: They had the same -- I mean, it's a
19 business decision that they made, which, I mean, it's not
20 alleged in the complaint, but Alere provides the monitor and
21 the strips, right, and then the meter that's at home, and then
22 the testing frequency is what ultimately pays for the meter.
23 So they made a business judgment to only allow patients into
24 the program who test frequently than more than once a month, so
25 either weekly or two to four --

1 THE COURT: And the theory is, that eventually pays
2 off the meter?

3 MR. KASSOF: It does pay off. That's --

4 THE COURT: And then do you have to give the meter
5 back? Do you know?

6 MR. KASSOF: I don't know. I --

7 THE COURT: You win it with enough strips?

8 MR. KASSOF: I don't know -- what's that?

9 THE COURT: You get to keep it with enough strips?

10 MR. KASSOF: Well, we know that Mr. Allen, after he
11 was exited from the Roche program, he actually tested at home
12 with the meter and strips, he alleges, so I suppose he still
13 continued to use the meter and the strips post- --

14 THE COURT: So you don't have to return it?

15 MR. KASSOF: -- I don't know. So, your Honor, at
16 Slide 6, all I did was put a comparison of the allegations with
17 Roche versus Alere just to frame it. And with Roche, Dr. Riegel
18 ordered the weekly tests, so Roche lets him in the program. He
19 then in July says Dr. Riegel and another physician signed on a
20 document that they submit to Roche that said, "We don't believe
21 it's medically necessary to test twice a week." So Roche says
22 that "If it's not medically necessary, then you're out of our
23 program." So contrast that with what happened with Alere.

24 So six months later Alere expressly told Mr. Allen
25 that "Our program requires twice a week. It's going to be up

1 to your doctor." They get a signed certification. So
2 Dr. Riegel signed the certification and ordered the testing.
3 Now he says that, not even effectively, he says, "I lied. That
4 wasn't true. At the time I didn't believe it was medically
5 necessary. Even though I told Alere, even though I knew it was
6 probably going to Medicare, I didn't believe it was medically
7 necessary for twice a week. I only think it was medically
8 necessary for once a week." He signed the certification
9 because he knew, I suspect, that if he said exactly what he
10 said to Roche, Alere would have said, "You're not allowed in
11 our program either." So he signed the certification certifying
12 that it's medically necessary to get into the Alere program so
13 he could do the finger stick once a month, so Alere let him
14 into the program.

15 The fact that Mr. Allen's physician, Dr. Riegel, in
16 his medical judgment, for whatever the reason, chose to sign
17 that certification and tell Alere that "It's medically
18 necessary for my patient to get tested two to four times a
19 month," Alere has the absolute right to rely on that. It
20 doesn't mean Alere submitted false claims.

21 THE COURT: All right, can you just jump ahead.

22 MR. KASSOF: Sure.

23 THE COURT: Are there any alleged false statements
24 made by you in your marketing of materials?

25 MR. KASSOF: No, your Honor.

1 THE COURT: All right.

2 MR. KASSOF: There's nothing in the complaint about
3 it.

4 THE COURT: All right, now, what about the fact that
5 they claim you billed for three -- that was the thing that was
6 unique to your client, that they billed twice for three rather
7 than the four.

8 MR. KASSOF: Exactly, because that's a coding --

9 THE COURT: The batch, the batch argument.

10 MR. KASSOF: I describe that as kind of like a coding
11 claim theory versus this overarching false form claim.

12 THE COURT: Yes.

13 MR. KASSOF: So there are two claims that they
14 alleged, and just to put it into context, there literally are
15 only two claims at issue in this one. So it is a claim
16 submitted on October 16, 2015, and a claim submitted on
17 December 2, 2016. That's it.

18 THE COURT: December 2, 2016?

19 MR. KASSOF: December 2, 2016, yes.

20 THE COURT: So a year later?

21 MR. KASSOF: Yes, one in October 16 of '15, December 6
22 of '16, so 14 months later. And we know that there's no
23 allegations that this was part of some massive scheme that
24 Alere was telling doctors --

25 THE COURT: So you've now looked into it. What

1 happened here? You're saying, was it a clerical error?

2 MR. KASSOF: No. I mean, outside the complaint, I
3 can --

4 THE COURT: Because I'm just saying, within the four
5 corners of the complaint, it was a false claim.

6 MR. KASSOF: I don't believe it was.

7 THE COURT: Why? But I'm just trying to figure out
8 what to do with it because if it's a clerical error which was
9 fixed, you go down one path in discovery. If it was a
10 practice, then you go down another path in discovery.

11 MR. KASSOF: So, first off, just to put it clearly
12 into perspective, we're talking about \$221 on two claims.

13 THE COURT: I get it, but if you extrapolate and it
14 was happening a lot --

15 MR. KASSOF: I don't think you can extrapolate, your
16 Honor --

17 THE COURT: Why?

18 MR. KASSOF: -- as the first point. So they submitted
19 Exhibit 1 to their opposition to the motion to dismiss. They
20 showed eight claims. They did a year period from March of '16
21 through March of '17, and they had eight claims. And they said
22 six of them were properly submitted after four tests. These
23 were the two that were not. So they've only identified two
24 claims. I think under 9(b) and the other governing law, you
25 can't -- there's no scheme -- in fact their allegations because

1 of that submission, their allegations belie the theory that
2 this was sort of a routine practice.

3 THE COURT: How long was he getting tested by you?

4 MR. KASSOF: Well, he was entered into the program, so
5 at least two years, at least two years.

6 THE COURT: So why wouldn't it make sense just to look
7 at the two years' worth of data and see whether this was just
8 an anomaly, inadvertent, not knowing, as opposed to just a
9 systemic -- I don't know what you'd call it -- accounting
10 practice, audit or some --

11 MR. KASSOF: I'm going to get there in two seconds --

12 THE COURT: Okay.

13 MR. KASSOF: -- as to why it's not, but you can't do
14 that anyway, though, your Honor, because they could have put in
15 all of the claims. They did it for '16. They did it for '16.
16 They identified --

17 THE COURT: Do they have all of the claims?

18 MR. KASSOF: They went to Medicare.gov. And this is
19 why I think the reason why the claim doesn't --

20 THE COURT: I see.

21 MR. KASSOF: They did two things. They pieced
22 together two pieces of information. They went on the Alere
23 website, and they gathered the tests that yielded numerical
24 values. When the strip was submitted into the monitor, it
25 yielded what its INR was. So they had the test dates that

1 yielded numerical values. They then went to Medicare.gov, and
2 they pulled Mr. Allen's claims that were submitted by Alere for
3 this entire year period, okay? And only two times over the
4 entire year did they say that Alere prematurely submitted
5 claims after three tests and not four. All the other ones they
6 say were perfectly fine as far as how they were submitted.

7 THE COURT: For one year?

8 MR. KASSOF: For one year, yes.

9 THE COURT: So two out of twelve.

10 MR. KASSOF: And I'm going to explain those two in a
11 second, but there's no allegations that it was ever submitted
12 any other time. They don't allege that it was because --

13 THE COURT: And you're saying they had access to it?

14 MR. KASSOF: They absolutely did, which they submitted
15 as Exhibit 1 to their opposition to the motion to dismiss.

16 THE COURT: All two years?

17 MR. KASSOF: They did one year. They did March '16 to
18 March '17, but there's no reason why they couldn't go further
19 than that.

20 Anyway, the reason why I don't think it states a false
21 claim anyway, though, your Honor, is that they do not allege
22 that he had no other failed blood tests or when -- what he
23 alleges is that the tests on the strip yielded a numerical
24 value. That's what they pulled off the website.

25 THE COURT: I didn't understand what that meant when

1 you said it yielded -- don't they all? I mean --

2 MR. KASSOF: No, they don't.

3 THE COURT: Why?

4 MR. KASSOF: Because you can prick your finger, put it
5 on the strip, put it into the meter, and you've used the strip
6 in the meter, but it may not yield a numerical value. It may
7 have been how the blood was placed on the strip, or for some
8 other reason, it didn't yield a number. It doesn't tell us
9 what your INR is.

10 THE COURT: Like a misfire, just it didn't --

11 MR. KASSOF: Right. It's deemed like a failed test.

12 THE COURT: It's not just whether it's above or below
13 a certain limit?

14 MR. KASSOF: Correct. The patient, though, has
15 tested. He's used one of his test strips into the meter, okay?
16 They don't allege that you can't count that as a test, as part
17 of the four that were submitted to Medicare. And Mr. Allen
18 doesn't allege that he didn't have any failed tests during
19 those periods of time -- this is outside the complaint -- but
20 the truth is, is that he did. We know that he did because he
21 submitted it to Alere. But he can't allege, he cannot
22 allege --

23 THE COURT: And you're allowed to submit a failed test
24 as one of your four?

25 MR. KASSOF: Yes, and they do not allege that Medicare

1 will not pay for inclusion of a failed test. They can't allege
2 that because that's not true. They don't allege that. And
3 they don't allege that he didn't have any failed tests during
4 that period of time.

5 THE COURT: So why isn't this -- I have a problem with
6 it because under 9(b), they have met their obligation, who,
7 what, when, where, and why, unlike with most of these --

8 MR. KASSOF: On those two.

9 THE COURT: -- on those two, and the question is,
10 those are false claims. I think there's no de minimis
11 requirement. And you're saying is that if you look at it, it
12 wasn't false at all. Don't I have to have something outside
13 the four corners of the record on it?

14 MR. KASSOF: Well, so I think they only get those two.
15 Okay, they only get those two, and I don't --

16 THE COURT: Well, they may get two years' worth of
17 discovery, though.

18 MR. KASSOF: Well, to me, that's misusing 9(b) on that
19 because you then are saying: Well, they've alleged two.
20 They've alleged that there are no other ones for that period of
21 a year, everything was properly submitted.

22 THE COURT: For a year.

23 MR. KASSOF: But then let them go find another year
24 and see if they can go get discovery on that, when they haven't
25 alleged anywhere any allegation suggesting that --

1 THE COURT: Okay, I hear your position. Thank you,
2 but we need to keep it going here, so --

3 So let me just jump to you. Is it true -- let me just
4 get through one issue -- there are no allegations of false
5 marketing with respect to Alere?

6 MR. DeNINNO: No. Alere is another defendant who
7 used -- again, the complaint cites the Heneghan article as an
8 example.

9 THE COURT: And where is it?

10 MR. DeNINNO: It's on their website. Again, the
11 complaint refers to it as marketing materials, but outside the
12 complaint, it's on their website, and it's used to support a
13 proposition that weekly self-testing has determined that timing
14 therapeutic range is increased. In the Heneghan article, it
15 doesn't -- it's not even -- and this is explained in the
16 complaint -- it's not even possible to determine how frequently
17 the subjects of that study were testing because it was a
18 retrospective analysis of fourteen different studies. I think
19 nine of them didn't require patients to disclose how
20 frequently --

21 THE COURT: And with respect to the form, there was
22 nothing within the four corners of the form? Was there
23 anything that you were challenging?

24 MR. DeNINNO: As far as the --

25 THE COURT: Alere.

1 MR. DeNINNO: The enrollment form, your Honor?

2 THE COURT: Yes.

3 MR. DeNINNO: Okay. No, I think the overarching point
4 with regard to the enrollment forms is that these enrollment
5 forms were used to implement the underlying false scheme, which
6 is that they're requiring doctors to order tests and they're
7 requiring patients to undergo tests at frequencies --

8 THE COURT: But there's no false marketing information
9 in it? The question is that they don't give you the option of
10 once a month? That's what the challenge is? I just want to
11 understand it.

12 MR. DeNINNO: Yes, with regard to the forms. I will
13 also say that the complaint does include other allegations of
14 false statements made by Alere. Those false statements were
15 made by Alere's representative to Mr. Allen to attempt to
16 persuade Mr. Allen to participate in their home INR testing
17 program. Specifically, it's attached to the complaint, the
18 email itself, and it's quoted in significant part in the
19 complaint that after Mr. Allen contacted Alere, a representative
20 named Mary Wages wrote back to Mr. Allen on January 13, 2015,
21 and said, "All the studies indicate that patients who have
22 tested more frequently have fewer adverse events." And the
23 complaint goes through and cites several other more recent,
24 more authoritative studies which don't find that. And so that
25 statement made by Ms. Wages to Mr. Allen in that email was

1 false, and it was made specifically to induce him to speak with
2 his doctor about participation in Alere's home testing program.

3 After Mr. Allen responded to Ms. Wages that he was
4 concerned that Medicare wouldn't cover testing that he hadn't
5 previously needed pursuant to his doctor's order, on
6 January 23, 2015, Ms. Wages responded, "Medicare will not
7 question frequency of testing," which again is not accurate.
8 And Mr. Allen went a step further with regard to Alere, and he
9 contacted the Medicare administrative contractor for
10 California, who confirmed in a written response to Mr. Allen,
11 which is also attached to the complaint, that Medicare does not
12 permit independent diagnostic testing facilities to order tests
13 on behalf of patients, and that they would question the tests
14 that were performed that weren't medically necessary. So again
15 it's our position that that's another false statement made by
16 Ms. Wages in an attempt to induce Mr. Allen, the patient, to
17 speak with his physician about participation in their program.

18 THE COURT: But did she ever speak to the physician?

19 MR. DeNINNO: We don't allege that anybody from Alere
20 ever spoke directly to the physicians at Buffalo Cardiology,
21 but in a situation like this --

22 THE COURT: It's like me listening to those ads every
23 night on TV, right?

24 MR. DeNINNO: Well, they're intended to make you go
25 talk to your doctor about whether or not --

1 THE COURT: Yes, they all are. Maybe we could just
2 get all of them and go back to cereal ads. I --

3 MR. DeNINNO: Not when they're truthful, though, your
4 Honor. I mean, truthful advertising is obviously permitted.
5 That's certainly not the allegation here. It's the falsity of
6 the statements that she made with regard to what, you know,
7 Medicare --

8 THE COURT: So the argument is, if you induce a
9 customer with false information and then he goes and asks for
10 it from his doctor, your argument is, that's a fraudulent
11 inducement?

12 MR. DeNINNO: Well, it's a false statement that's
13 material to the submission of false claims.

14 THE COURT: Maybe. I mean, the doctor here seemed to
15 have pretty strong views about it, so I'm not sure. At least
16 with Riegel, he seemed to know what he was doing.

17 MR. DeNINNO: Well, again, the false statements are
18 specific examples that are indicative of the policies that
19 they're imposing on every patient. I mean, these are specific
20 examples of false statements that were made. And the complaint
21 alleges, again, that it's the underlying policy of requiring
22 patients to test their INR at a frequency that the defendants,
23 that Alere determined that violates the regulations and leads
24 to a false claim, and so --

25 THE COURT: What about these strips; in other words,

1 whether there's three or four? We may need more evidence about
2 it, but do you agree with what your brother says here, which is
3 that essentially you're allowed to bill for strips that fail?

4 MR. DeNINNO: I don't agree with that, and I don't
5 agree that we don't allege that. The billing code that they
6 have to use to submit these claims is HCPCS Code G0249, which
7 requires the IDTFs to provide services and supplies for four
8 tests and to actually report the results of those tests to the
9 physician. And, again, this is a factual allegation that's not
10 included in the complaint --

11 THE COURT: So I just want to understand. So if you
12 have a failed test -- as he says, you know, there wasn't enough
13 blood, it was placed in the wrong spot, the equipment
14 malfunctioned, whatever -- there was a test, a strip was sent
15 in, and it got no numerical value, is there a regulation that
16 says what you're supposed to do about that?

17 MR. DeNINNO: No, there's not. And I think there
18 might be, and correct me if I'm wrong, but I think that what
19 Mr. Kassof said was that the strips are put into the machine at
20 home, and if the test does fail, it's up to the patient to call
21 that in to somebody to let them know it failed. They're not
22 connected or they're not mailed. There's a step where the
23 patient reports that, so --

24 THE COURT: Well, how would he know if it just wasn't
25 enough blood, for example?

1 MR. DeNINNO: I think the machine -- my understanding
2 is that the machine puts an error code rather than a result on
3 its interface screen.

4 THE COURT: I'm just worried that this issue may need
5 some discovery, but not a lot.

6 MR. DeNINNO: Well, your Honor, I also -- I wanted to
7 correct one issue for the record. The tests were not 14 months
8 apart. They were consecutive tests. They were tests on
9 October 16 of 2016, not 2015, and the very next test on
10 December 2 of 2016.

11 THE COURT: All right, I see. I see. But that just
12 may have been a --

13 MR. DeNINNO: Well, we allege, you know, in light of
14 all of the other underlying actions and conduct that are
15 contained in the complaint, that this is just another of
16 Alere's actions which are intended --

17 THE COURT: Do you have the other year's worth of
18 billings?

19 MR. DeNINNO: I don't have the other year's worth of
20 billings, and I'm not sure whether they're available. The
21 exhibit that was attached to the complaint was provided because
22 apparently on Alere's website, they continued to report the
23 previous year's test results, and that happened to be what was
24 available at the time.

25 THE COURT: So let's suppose I order them to produce

1 as part of automatic disclosure the two years' worth of data,
2 and these are the only two, and they also present evidence that
3 the fourth one was a failed test, does the claim go away on
4 summary judgment?

5 MR. DeNINNO: Are you talking about just Mr. Allen,
6 your Honor? I mean, they're obviously providing these tests to
7 tens of thousands of patients, and the allegation is that this
8 was --

9 THE COURT: Well, but if they prove everything was
10 kosher, then there's no inference of a fraudulent scheme
11 because the one or two examples of a fraudulent claim that you
12 have, which if it turns out that it's not fraudulent, it
13 doesn't support an inference that it was broader. If it turns
14 out it was, perhaps it does, so -- anyway, that's what I'm
15 thinking about.

16 MR. DeNINNO: Well, I would also say with regard to
17 that, your Honor, the idea that -- we certainly don't agree
18 that a failed test can be counted as one of the four. They
19 have to report actual results.

20 THE COURT: I would just have to see the regs. I'm
21 not going to jump into that here.

22 MR. DeNINNO: Okay, I understand that, but --

23 THE COURT: But it may not be fraudulent. In other
24 words, it may be a misunderstanding of the reg if it's not
25 clear. You say there's nothing clearly on point.

1 MR. DeNINNO: No, the regulation says that the test
2 results have to be reported. It's the billing code. It's not
3 a regulation. The billing codes are adopted by the CMS program
4 manual. But that's where the direction comes that the IDPFs
5 have to actually perform and report. And if they are, if as
6 has been suggested that they are --

7 THE COURT: So you're saying the fourth, they should
8 just report this is failed?

9 MR. DeNINNO: No, I think -- and I think that what
10 happens when you have a failed test is, you immediately use
11 another finger and do another test. You still have to perform
12 the test. You can't just not --

13 THE COURT: Yes, just we're so far beyond the record,
14 I just don't know.

15 MR. DeNINNO: And, right, and that's not what we
16 allege. But if in fact that is what they're doing and they're
17 reporting failed tests as though they're one of the four tests,
18 then that actually would reveal a more widespread systematic
19 failure that would require more discovery to find out whether
20 or not that's something that's being done --

21 THE COURT: I don't know, but I'll think about that
22 one. I'll think about that one. All right, thank you.

23 MR. DeNINNO: Thank you.

24 THE COURT: All right, so now the question is, we got
25 going around what time, 10:00, 10:15 or something? What do we

1 want to do here? We have two more or three more?

2 MR. KRAUS: 10:13 we started, your Honor.

3 THE COURT: 10:13? Well, thank you. Very good. Do
4 you want to do one more and then we take a break?

5 MR. KRAUS: I'm fine. It's your call, your Honor.

6 THE COURT: Why don't we have you go, and then we'll
7 take a break.

8 (Discussion off the record.)

9 MR. KRAUS: Thank you, your Honor. On behalf of
10 mdINR, and I won't repeat what's been said already. The points
11 that I would make on behalf of mdINR are, there is no falsity.
12 Our enrollment form is explicit that we are for weekly testing
13 patients only. So the complaint uses a lot of conclusory
14 labels like "no exercise of independent medical judgment" and
15 "coercion," but there is no coercion, and there is no lack of
16 independent medical judgment when we tell the physician exactly
17 the service that we provide and ask the physician if he or she
18 wants to prescribe that. It's very straightforward. It's
19 nothing misleading, no --

20 THE COURT: Is there any false information being
21 alleged against you?

22 MR. KRAUS: I think only to the extent that they
23 suggest one thing, that same study. It's I think in
24 Paragraph 1... There's a paragraph, and I'll get you the cite,
25 your Honor, but there's one paragraph where they say we use

1 that same study. I don't believe that a -- I think it's
2 Paragraph 130.

3 THE COURT: Is it on your website?

4 MR. KRAUS: It's not alleged. I don't believe it is,
5 but it's not alleged, so I can't say for sure.

6 THE COURT: Do you have any information on the form
7 that's being challenged?

8 MR. KRAUS: Yes, and it's explicit. It says exactly
9 what we do. We say what we do, and we mean what we say. It's
10 on --

11 THE COURT: An elephant is faithful one hundred
12 percent?

13 MR. KRAUS: That's where I was going. Exhibit TT, and
14 it says explicitly, "I understand --" this is under the
15 statement, quote, "Statement of medical necessity and
16 prescription," and it goes through a number of different
17 statements but then ends, "I understand that mdINR's PT/INR
18 monitoring service is for weekly testing patients only."

19 THE COURT: So, okay, thank you.

20 MR. KRAUS: There you go. So that's --

21 THE COURT: It's almost like -- you're the first one
22 that there's no claim alleged.

23 MR. KRAUS: No. That's the other thing. So there's
24 no falsity. There's no 9(b). This is not a difficult 9(b)
25 case at all. If you apply what you did in *Verrinder*, it's out.

1 It's not -- you don't even get access to the relaxed rule under
2 *Duxbury* because this is not third-party submission, this is not
3 indirect submission; it is direct submission alleged by mdINR;
4 and they have zero physician, zero patient, zero claims. It
5 just doesn't state a claim.

6 If you look at what the First Circuit just did in
7 *Nargol* in 2017, *Nargol* says *Karvelas* is still the law of the
8 circuit, just like you did in *Verrinder*, and it's a direct
9 claim and there's no allegations. Even, you know, I could talk
10 about other cases that they cite. None of them get them to a
11 place where they can satisfy 9(b). If you look at the *Ge* case,
12 the *Ge* case specifically says that the First Circuit is
13 doubtful that an "all claims," quote/unquote, theory without
14 providing any specifics would have passed 9(b).

15 THE COURT: Thank you.

16 MR. KRAUS: You're good?

17 THE COURT: Yes, I'm good.

18 MR. KRAUS: Public disclosure, we do think that
19 there's a public disclosure, and they're out on the public
20 disclosure bar.

21 THE COURT: If I get there. This is a hard one for
22 you because there are no claims.

23 MR. DeNINNO: I'm sorry?

24 THE COURT: There are no claims that you've alleged.

25 MR. DeNINNO: Well, we allege that -- as he pointed

1 out, we allege that all of the claims were false. Especially
2 with regard to mdINR, they require every patient who
3 participates in the program to test exactly weekly. That's
4 exactly what's prohibited by 410.33(d), which --

5 THE COURT: But only people who sign up and a doctor
6 says needed. I mean, are you alleging any false information?

7 MR. DeNINNO: They do cite the Heneghan study. It's
8 again, like I said --

9 THE COURT: It's on their website?

10 MR. DeNINNO: It's on their website. They cite it for
11 the proposition that self-testing may reduce adverse events,
12 which is again, as I explained in response to Roche,
13 specifically what was found to be insufficient by the authors
14 in 2012.

15 And, you know, your Honor, the other point is that
16 they are out there; they are offering these services to every
17 patient. They're not limiting it to people who only require
18 weekly testing. They --

19 THE COURT: No, but it's to every patient who had a
20 doctor sign a form.

21 MR. DeNINNO: Right, but they're not --

22 THE COURT: You've got to get to the doctor somehow in
23 order to make this, you know, like a kickback, a fraud or
24 something.

25 MR. DeNINNO: The doctors aren't being -- the signing

1 of the form can't be a valid order because the doctors don't
2 have any independent discretion. This is exactly what the
3 Office of the Inspector General gets at with its guidelines,
4 which again were cited by the *Boston Heart* case as being
5 binding upon the laboratory. If the OIG requires forms to be
6 developed in a way that promotes the conscious ordering of
7 every individual test by the physicians --

8 THE COURT: I mean, I get your skepticism. Suddenly
9 the 2008 Medicare regulation permits this expansion in funding,
10 and, whoops, they'll only provide weekly or biweekly or
11 nothing. I understand that you believe they've put this
12 pressure on the doctors in order to afford the doctors'
13 patients some access that they didn't otherwise have. I
14 understand that. It's just a much harder claim than any
15 because there are no false claims for at least three of these
16 companies, four of these companies, none.

17 MR. DeNINNO: I have to respectfully disagree. Again,
18 your Honor, the allegation is that all the claims are
19 necessarily false when you don't allow a physician to make an
20 independent judgment.

21 THE COURT: I'm just not going to accept that
22 argument. I mean, have fun at the First Circuit. Just you've
23 got to have something that shows that there was a connect to a
24 doctor that made them fraudulently prescribe, and I'm just not
25 sure one article on a website is enough, compared to what I've

1 seen before, which is so much more of a weighty set of
2 evidence.

3 MR. DeNINNO: There is an additional false statement
4 with regard to mdINR. Their representative, again, after being
5 contacted by Mr. Allen and Mr. Allen specifically asking
6 whether they would fill a prescription, as his doctor believed
7 was medically necessary for I believe once and sometimes twice
8 per month, on January 13, 2015, a Teresa Hoff Cimiluca
9 responded that he should be one hundred percent covered by our
10 service by Medicare, despite the fact that she had just been
11 informed that it wasn't medically necessary for him to undergo
12 testing any more than once, sometimes twice per month pursuant
13 to Dr. Riegel's instruction.

14 THE COURT: All right, that's helpful.

15 MR. KRAUS: Your Honor, if I might, if you look at the
16 statement that counsel just referred to, the statement says,
17 "We are weekly testing only. Therefore, you and your physician
18 have to agree to weekly testing to use our service." There's
19 nothing misleading about it. It says exactly what the form
20 says.

21 THE COURT: Well, and plus, right, "and you'll be
22 covered one hundred percent"?

23 MR. KRAUS: If it's medically necessary and you test
24 within the criterias, then that will be covered.

25 THE COURT: How many people do I have left?

1 MS. SHANAHAN: Three of us, your Honor.

2 THE COURT: Three of you. Are they -- well, I think
3 we should take a ten- or fifteen-minute break, and then we'll
4 come back. Okay, thank you.

5 THE CLERK: All rise.

6 (A recess was taken, 11:21 a.m.)

7 (Resumed, 11:44 a.m.)

8 THE COURT: Okay.

9 MS. SHANAHAN: Good morning, your Honor. Sara
10 Shanahan for Patient Home Monitoring. PHM is similarly
11 situated to mdINR. There are no false claims identified.
12 Patient Home Monitoring did not provide any services to
13 Mr. Allen, and there aren't any allegations in the complaint
14 that would point to any other patient or doctor tied to a
15 particular claim.

16 Similarly, we concur with the arguments that have been
17 made by the other defendants that there's no obligation for
18 Patient Home Monitoring to provide services beyond the niche
19 that it's designed its business to meet, which is weekly
20 testers. And the --

21 THE COURT: Do you know, does the person keep the
22 meter at the end in your company?

23 MS. SHANAHAN: When it's done with the testing?

24 THE COURT: Yes.

25 MS. SHANAHAN: My understanding is that the meter is

1 given to the patient, and then the strips get re- --

2 THE COURT: And when the testing necessity is over,
3 does it get returned?

4 MS. SHANAHAN: I don't know the answer to that.

5 THE COURT: No one seems to. We couldn't figure that
6 out.

7 Is yours?

8 MR. PEARLSTEIN: So I think the patient keeps it. As
9 indicated here with Mr. Allen, he kept the Roche meter.

10 THE COURT: So any alleged misleading marketing
11 information?

12 MS. SHANAHAN: So there is the same allegation in
13 Paragraph 130 of the complaint that PHM somehow marketed the
14 2006 Heneghan article, but there aren't any additional
15 allegations related to who, what, when, where, how.

16 THE COURT: Anything on your form other than the form
17 itself?

18 MS. SHANAHAN: The form is very straightforward, your
19 Honor. It specifically identifies weekly testing. It
20 specifically identifies in the certification --

21 THE COURT: But no representations as to the medical
22 necessity of it?

23 MS. SHANAHAN: I mean, there's a specific
24 certification at the bottom that states that the doctor is
25 certifying that the testing is medically --

1 THE COURT: But no alleged misrepresentations within
2 the body of the form?

3 MS. SHANAHAN: I don't believe so, other than the
4 general argument that it should have been a blank instead of
5 identifying weekly testing.

6 THE COURT: All right, thank you. All right.

7 MR. DeNINNO: Your Honor, with regard to Patient Home
8 Monitoring, their website -- and their website is linked in
9 their motion to dismiss, so I think it's appropriate to bring
10 up that their website does contain a citation again to that
11 2006 Heneghan article, again stating that patients capable of
12 self-monitoring could benefit from a one-third reduction in
13 death from all causes. Again, we think that that is a
14 statement that -- in this particular case, I think that's a
15 statement that doesn't exist at all, even in the 2006 article,
16 just even taking out of the equation the fact that the authors
17 question their own previous conclusions later on, well before
18 this statement remained published on their website.

19 PHM, their complaint also includes a PowerPoint
20 presentation that PHM gave to its investors -- I believe it's
21 dated in 2010 -- in which they indicate that they're going to
22 set up their business as a business systemization --

23 THE COURT: As a business?

24 MR. DeNINNO: Business systemization for physicians
25 rather than a health benefit marketing of their services to

1 physicians. This PowerPoint presentation suggests that
2 individual cardiology clinics might realize a benefit of
3 \$250,000 per year if they refer their patients into the PHM
4 home monitoring program.

5 THE COURT: How? I didn't understand that. Why would
6 it be a profit center for a doctor?

7 MR. DeNINNO: Because the doctors get to bill -- it's
8 the very next HCPCS code, which is G0250 -- they get to bill
9 separately for interpreting the results.

10 THE COURT: I see, because one would think that the
11 actual taking of blood at the clinic and then interpreting the
12 results would actually be more profitable.

13 MR. DeNINNO: That's -- I don't think that's --

14 THE COURT: No, I'm just --

15 MR. DeNINNO: -- an unreasonable assertion. That's
16 just what they represent.

17 THE COURT: Like, we were trying to figure out why
18 does a hospital take blood intravenously, whereas you could do
19 a pinprick, and we were wondering whether that's because you
20 could charge more money for it, thinking that hospitals are not
21 immuned to this. I would have thought that the clinic would
22 have preferred people coming in; they can charge for the nurse
23 and the taking of the blood and the reading.

24 MR. DeNINNO: I don't know the answer to that
25 question, your Honor. I know that --

1 THE COURT: Anyway, I just assume everybody is
2 selfishly motivated, as long as it doesn't hurt the patient.
3 I'm not saying anyone wants to hurt a patient, but that they
4 try and get the one that's most profitable. No, you don't
5 know.

6 Anyway, so that that's what you're relying on is the
7 investment PowerPoint. Any evidence that that gets to a doctor
8 at all?

9 MR. DeNINNO: Well, I mean, the admission that they
10 make in their presentation to investors is that this is how
11 they're going to market their services. And, your Honor, I
12 think this also brings up a different point we didn't discuss
13 earlier this morning, which is that there is an obligation
14 under the Social Security Act to provide services economically.
15 It's Section 42 U.S.C. 1320c-G(a)(1).

16 THE COURT: Good for you.

17 MR. DeNINNO: I know, it's a mouthful. Obviously I
18 had to write it down. But there's precedent in this district
19 for applying that regulation to find that claims are false, or
20 at least not dismissed in a complaint alleging the claims are
21 false, when laboratories performing blood tests, incidentally,
22 developed protocols to maximize their profits. That's the
23 *Kneepkins v. Gambro Laboratories* case. And there's other
24 examples from outside the district as well. There is the
25 *Amedysis* case which --

1 THE COURT: Yes, but I can't -- first of all, you
2 didn't sort of allege it that way, that I remember anyway.
3 There's so much briefs on it. But at the end of the day, in
4 terms of economically, they're saying they need to have at
5 least four to pay off the equipment.

6 MR. DeNINNO: Well --

7 THE COURT: So if I'm going to jump into the economics
8 of it, don't I have to know those kinds of things?

9 MR. DeNINNO: Yeah, I mean, I certainly think that --
10 well, to know, obviously we'd need more information, and that's
11 a factual issue that's beyond the complaint. I think that
12 answers its own question, which is that it shouldn't be a
13 grounds for dismissal at the --

14 THE COURT: Did you allege that violation?

15 MR. DeNINNO: We alleged throughout the complaint that
16 their policies were created to maximize their profits. We
17 didn't specifically cite to that --

18 THE COURT: To that statute.

19 MR. DeNINNO: -- to that statute, but throughout the
20 complaint, it indicates that the defendants had profit
21 maximization rather than patient health, and especially in the
22 paragraph discussing this PHM --

23 THE COURT: I'm assuming that's true, by the way, but
24 I'm not sure that's enough to be a False Claims Act violation.
25 It may be some other statutory violation, but you do have to do

1 something false.

2 MR. DeNINNO: Well, the falsity is that they are
3 intentionally culling out patients who are less profitable, and
4 they're not disclosing this when they're submitting their
5 claims that they're only offering services to patients. This
6 is one of these half-truths or critical omissions that the
7 Supreme Court found in *Escobar* that still can amount to a false
8 claim.

9 THE COURT: With respect to PHM, I'm correct that you
10 don't know of any specific false claim, and you're claiming all
11 the claims are false?

12 MR. DeNINNO: That's correct, your Honor.

13 THE COURT: And that's true for the rest of them?

14 MR. DeNINNO: Right. Mr. Allen only actually
15 performed testing as part of the Roche and Alere testing
16 programs, but --

17 THE COURT: That's right, and there's no other
18 information. All right, thank you.

19 All right, next one.

20 MS. THORVALDSEN: Good afternoon, your Honor. Kara
21 Thorvaldsen. I have two of the defendants, US Healthcare
22 Supply and also Advanced Cardio Services.

23 Like Patient Home Monitoring and like mdINR, there are
24 no specific claims at all alleged as to either of my clients.
25 Mr. Allen did not receive services either from US Healthcare or

1 from Advanced Cardio Services. He never enrolled in their
2 programs and merely received some information from each of them
3 that he actually sought out. There's no allegation that either
4 of my clients ever contacted any physician, whether it's
5 Mr. Allen's or anybody else in particular.

6 THE COURT: Do you have this article on your website?

7 MS. THORVALDSEN: Your Honor, according to --

8 THE COURT: Websites, I should say, since you're
9 representing two companies.

10 MS. THORVALDSEN: I do, and I'm sorry if addressing
11 them both together confuses things, but in Paragraph 130 of the
12 First Amended Complaint, my two clients, Advanced Cardio and US
13 Healthcare Supply, are the two defendants who actually are not
14 identified as having relied on and promoted this 2006 Heneghan
15 article, so my two clients specifically did not rely on that.

16 THE COURT: And is there anything on your form that's
17 alleged to be false other than not giving them the option of
18 once a month?

19 MS. THORVALDSEN: So with respect to US Healthcare
20 Supply, there's no enrollment form provided with the complaint
21 or alleged at all. What's alleged with respect to US Healthcare
22 is that when Mr. Allen contacted that company, he advised them
23 that he would like to test on a monthly basis. They advised
24 him that as an initial matter, they only accept weekly or
25 biweekly testers, and that unless his doctor ordered that

1 frequency, he wouldn't be eligible to enroll in their program.
2 That's sort of where that one was left.

3 With respect to Advanced Cardio Services, there is an
4 enrollment form. Their enrollment form, which is attached to
5 the complaint as Exhibit JJ to the Allen affidavit, states
6 under "Prescription and Certificate of Medical Necessity," it
7 has a doctor certify that "It's medically necessary for this
8 patient to self-test weekly in order to maintain a stable INR
9 and avoid complications associated with Warfarin therapy." And
10 it also states, "The patient's medical records support the
11 medical need for this service," and it certifies that
12 "Physician and patient understand that this service is for
13 weekly self-testing patients only." So it's very clear, it's
14 very transparent, as with mdINR.

15 The one caveat that I would add to that, in candor, is
16 that in probably 5-point font under the test frequency
17 provision on the form, it says, "Medicare recommends weekly
18 testing."

19 THE COURT: So that's false, right?

20 MS. THORVALDSEN: Your Honor, I do not believe that
21 there is a specific recommendation from Medicare that weekly
22 testing is indicated, but I would submit that that on the form
23 is superfluous once the doctor has certified that weekly
24 testing is necessary for this particular patient, and that both
25 the patient and physician understand that this service is only

1 for weekly testing patients. And, of course, your Honor,
2 there's no evidence of this particular form being used by, seen
3 by, or influencing any physician that used ACS's services.

4 THE COURT: But in some ways yours presents the
5 hardest case because it's the one form that actually -- it's
6 not like something is on a website, and maybe a doctor saw it
7 or a doctor didn't see it. That's the form the doctor has to
8 sign, right?

9 MS. THORVALDSEN: That's correct. This provides for
10 the physician to order the weekly testing. But, again, the
11 form itself specifies that the physician has made the
12 determination that this particular patient that is being
13 enrolled requires weekly testing.

14 THE COURT: That's the hardest one I've heard yet,
15 other than the strip thing, so --

16 MS. THORVALDSEN: Again, your Honor, there is no claim
17 that any services were provided under this form. The form was
18 provided to Mr. Allen in response to him reaching out to --

19 THE COURT: Well, his claim is one of these
20 exceptions. They claim that everything was induced basically.

21 MS. THORVALDSEN: Correct, your Honor. I think
22 plaintiff's theory as to Advanced Cardio Services would be that
23 every claim that was ever submitted by Advanced Cardio Services
24 for weekly INR testing, which would have been all of the
25 services that they ever provided, would have been false based

1 on this one statement in the enrollment form.

2 THE COURT: Well, I don't know if I buy that, but is
3 it foreseeable that some are?

4 MS. THORVALDSEN: Your Honor, I don't believe that's
5 the standard, and I think it would be implausible, given the
6 fact that, again, by the time the doctor is ordering the weekly
7 testing, the doctor has already made the determination that the
8 particular patient being enrolled requires weekly testing.

9 THE COURT: Is that still on the form?

10 MS. THORVALDSEN: I can't answer that, your Honor. I
11 don't know.

12 THE COURT: It shouldn't be.

13 MS. THORVALDSEN: Duly noted, your Honor.

14 THE COURT: Okay, all right, thank you.

15 MS. THORVALDSEN: Thank you, your Honor.

16 MR. DeNINNO: Your Honor, I think, you know, that's an
17 important point. These forms, the way that the form was
18 communicated to Mr. Allen was that it was emailed to him after
19 he inquired about the Advanced Cardio Services. This is the
20 form that they used, that they provided to all patients and to
21 all physicians in order to have them enrolled in their program;
22 and it contains, as I think we've just established, a false
23 statement that's necessarily associated with every claim that
24 they submitted.

25 THE COURT: But the other ones, she's got the weakest

1 and the strongest case you've got because the other one doesn't
2 even reference the article, what's it, US Health. It doesn't
3 reference the article, doesn't -- there's nothing.

4 MR. DeNINNO: US Healthcare, I believe they don't
5 even -- I'm not sure they have a website that discusses this at
6 all, but --

7 THE COURT: You don't have the enrollment form. You
8 don't have anything false that was sent. You have nothing.

9 MR. DeNINNO: Oh, your Honor, for US Healthcare we do.
10 We have -- when Mr. Allen contacted US Healthcare, he again
11 disclosed that he needed testing pursuant to his physician's
12 order, which is weekly or biweekly, again, as we discussed
13 earlier, based on the Buffalo Cardiology algorithm and what his
14 previous tests had established; and a Kathryn Famularo
15 responded and said that he should be a hundred percent covered.
16 And then Ms. Famularo also told Mr. Allen that if he agreed to
17 test weekly for the first month, or however long it took them
18 to recoup the cost of the testing meter, that then they would
19 honor the prescription issued by his treating physician, which
20 again establishes that there's necessarily a false claim with
21 respect to every patient. If they're requiring every patient
22 to test weekly until they make sure that each patient is
23 profitable, and then they start following doctors' orders,
24 those initial claims have to be false. They're admitting that
25 they're taking away the doctor's ability to prescribe testing

1 pursuant to their independent judgment.

2 THE COURT: Thank you.

3 MR. DeNINNO: May I --

4 MR. GELB: Your Honor, Richard Gelb --

5 THE COURT: Did you have something else? I'm sorry.

6 MR. DeNINNO: I also wanted to say that Advanced
7 Cardio Services -- we kind of just skipped right over the US
8 Healthcare -- although there's not the statement on their
9 website, they do distribute a brochure to patients. And this
10 is another document that's produced to Mr. Allen just based on
11 his initial inquiry, and the brochure contains basically the
12 same statement that the other websites have, which is,
13 "Medicare has determined that weekly testing compared to
14 traditional monthly lab tests can lead to fewer complications
15 associated with coumadin therapy," which, again, Medicare
16 hasn't made any such determinations. The only --

17 THE COURT: Who does that brochure get distributed to?

18 MR. DeNINNO: In the amended complaint, it got
19 distributed to Mr. Allen as soon as he inquired about services,
20 and the allegation is that that's submitted to any patient or
21 any physician who inquires about services as part of --

22 THE COURT: Thank you. Thank you. I'm sorry, I
23 jumped over that. Mr. Gelb.

24 MR. GELB: Thank you, your Honor. Your Honor, with
25 respect to CardioLink, this is a situation, based on the

1 complaint, where the realtor (Sic) is trolling for cases.
2 There's no suggestion that he ever intended to use the
3 services --

4 THE COURT: The relator?

5 MR. GELB: Yes, the relator -- that he intended to use
6 the services and that he attempted to use the services. The
7 form itself that he cites in the record has a field for
8 "other." There's no allegation that if a doctor was coerced
9 not to fill in the field "other," there's no allegation that
10 any claim was submitted inconsistent with any doctor's
11 prescriptions.

12 In addition, the DVD that they refer to, there's no
13 allegation of the exact circumstances. A DVD was never
14 delivered to Mr. Allen.

15 THE COURT: Why are you talking about the DVD?

16 MR. GELB: Well, he alleges that our client,
17 CardioLink, does not make face-to-face visits but rather uses a
18 DVD.

19 THE COURT: To sell the product to the doctor?

20 MR. GELB: Well, no. To instruct on how to use the
21 product.

22 THE COURT: How to use it. And so what does it say on
23 it? You know, you assume I know -- there are so many
24 defendants here and so many different allegations, I just want
25 you to remind me. What is the false statement alleged in the

1 DVD?

2 MR. GELB: There's no false statement alleged in the
3 DVD. He's never even gotten a DVD. I mean, I don't want to go
4 beyond the complaint, but in fact the DVD --

5 THE COURT: So are there any alleged false statements
6 made by you? You, your company, I mean?

7 MR. GELB: No. No, your Honor, there's no false
8 statements that are specified. There's nothing to indicate
9 that doctors were influenced on decision-making. There's no
10 marketing materials cited. There's no actual documents that
11 would support a false statement or a false record. It's just a
12 phone call for what they put in quotes in the complaint, "the
13 tech division of CardioLink." There's no allegation of what
14 the tech division does. There's no allegation of what
15 authority the person had to whom he spoke. There's no
16 allegation that the person he spoke to had any knowledge about
17 claim submission. There's no allegation that the person he
18 spoke to had any knowledge about training, and there's no
19 allegation that the person he spoke with would have any
20 authority to bind the company.

21 THE COURT: But what did the person say allegedly?

22 MR. GELB: Well, what is characterized is, he said
23 that they submit forms even if they don't do testing; that if
24 the doctor puts in for testing on a less frequent basis, they
25 still submit forms.

1 THE COURT: False forms? I'm not understanding.

2 MR. GELB: In other words, what they're alleging is --

3 THE COURT: That even if he's only tested once a
4 month, they'll put in claims for the other three weeks? Is
5 that it?

6 MR. GELB: Yes, but there's no evidence of that.

7 THE COURT: I'm just trying to figure out what the
8 allegation is.

9 MR. GELB: What it says is, "However, as Allen
10 discovered during his conversation with Sheffel --" that's the
11 individual from CardioLink -- "goes a step further than each of
12 the other defendants, IDTFs, at least explicitly, and submits
13 the maximum number of claims for reimbursement to Medicare per
14 patient regardless of whether the patient actually took the
15 test."

16 There's no reliable evidence to meet the standards of
17 9(b) and 12(b)(6). The form itself has a provision for
18 "other."

19 THE COURT: Okay, thank you.

20 So what was the claim against CardioLink?

21 MR. DeNINNO: Your Honor, with regard to the DVD
22 issue, the national coverage determination that permits all of
23 the defendants to submit bills for home INR testing requires
24 that they assure that patients are provided face-to-face
25 training on the use of the testing meter before they're ever

1 eligible to submit any claim for reimbursement for testing.
2 When Mr. Allen contacted CardioLink, he was told that the
3 training would be provided by mailing him a DVD. Mailing a DVD
4 obviously is not face-to-face training, and therefore the
5 allegation is that CardioLink was never eligible to submit any
6 claims for home INR testing because they never satisfied the
7 prerequisite that face-to-face training was provided to
8 patients.

9 THE COURT: So this is a really different kind of
10 claim. This isn't about false marketing or a coercive form.
11 This is about failure to give training face-to-face.

12 MR. DeNINNO: Right, and that's a prerequisite to
13 submitting any claims at all. That's one of the allegations
14 against CardioLink. As he also discussed, when Mr. Allen
15 called, he was told by the CardioLink vice president of the
16 tech division, which is how he identified himself, that, first
17 of all, that CardioLink was required by Medicare to submit
18 tests at least every two weeks or at least twice a month, which
19 isn't true. Medicare doesn't require bills to be submitted to
20 them at any frequency. They allow bills to be submitted after
21 four tests are performed. And then this vice president also
22 informed Mr. Allen that, because Mr. Allen inquired whether or
23 not he could continue testing at the frequency that his
24 physician prescribed, that he could test at whatever frequency
25 he wanted, but that CardioLink was going to continue submitting

1 bills pursuant to their schedule, which is as though Mr. Allen
2 was testing every week.

3 THE COURT: Okay.

4 MR. GELB: Your Honor, if I may?

5 THE COURT: Yes.

6 MR. GELB: We're confined to the complaint, so we
7 would dispute these allegations. The point that I'm making is
8 that even if you accept it as true, there's no -- it's
9 speculative what actually occurred. In other words, it's not a
10 situation where someone consumes services and did not get
11 training. It's an isolated phone call with somebody that he
12 happened to interpret the conversation, but it's totally
13 speculative of --

14 THE COURT: Well, it's not speculative. It's what the
15 guy said, but the question -- the question I'm struggling with
16 is without even one claim. I don't think the First Circuit
17 has -- it does have a more flexible standard, but without even
18 one claim, even assuming some fraudulent statements by an
19 employee or on the form, what do I do? I mean, that's the
20 legal question. I have to assume it's true that your person
21 said that they were doing something fraudulent.

22 MR. GELB: Not fraudulent.

23 THE COURT: Well, it's what he says he's going to do,
24 is that "Regardless of the test, I'm going to submit the
25 claim." That's fraudulent, right?

1 MR. GELB: Yeah, but if the form says "other," then
2 the only way the claim can be false is if the doctor's form was
3 altered, and there's no allegation that that occurred. There's
4 no allegation that --

5 THE COURT: I understand that, and that's why that's
6 the very narrow legal question I need to answer. Either
7 whether it's because of the form was bad for cardio services or
8 your employee said something bad, does that case go forward
9 without even one claim?

10 MR. GELB: The form is distinguished from the others
11 because --

12 THE COURT: You're not hearing me.

13 MR. GELB: I'm sorry.

14 THE COURT: At least if you took what that employee
15 said as true, "It doesn't matter what you fill in on the form,
16 we're going to submit for claims, for multiple claims," you
17 know, per month, the four, then that's fraudulent; but I don't
18 have any evidence that it actually happened. And the First
19 Circuit has been pretty rough on saying you've got to have some
20 sense that there was at least one claim that was fraudulent,
21 and that's what I'm struggling about.

22 MR. GELB: And, your Honor, if I may, I think the case
23 law also says that the complaint should not be a vehicle to
24 find evidence to meet the standards of 9(b).

25 THE COURT: I understand that, but I -- I understand

1 that. So what is the big case you're relying on to say even if
2 there's not one claim that's allegedly fraudulent?

3 MR. DeNINNO: Well, your Honor, there are a number of
4 cases in this circuit that have found that in situations where
5 the underlying conduct necessarily results in falsity in the
6 claims submitted to the government, that it's not necessary to
7 plead specific false claims.

8 THE COURT: I understand that. I actually had one of
9 these yesterday where it just seems immediately foreseeable,
10 but here it's just really one big step removed from that. I
11 mean, here's some -- so I'm struggling with that, I have to
12 tell you. Is there a case where there's no claim, false claim
13 at all?

14 MR. DeNINNO: Sure, your Honor. I believe that the
15 *United States ex rel Hutcheson v. Blackstone* is --

16 THE COURT: *Hutcheson* is what you're relying on,
17 because I know there's some that have tried to be more
18 flexible, but it's only if you know for a fact --

19 MR. DeNINNO: Well, I agree, but that is what we
20 allege with regard to these underlying policies that mandate
21 the tests to be performed at the frequency --

22 THE COURT: Can I tell you what the problem is? I
23 don't think I accept your core, if I haven't been clear, your
24 core tenet that, you know, just because they're requiring at
25 least bimonthly, that in and of itself is a False Claims

1 violation. I think, as long as you have a doctor signing off
2 on it who hasn't been induced by false information, that that's
3 not a False Claims Act violation.

4 However, I've now got an example of one false form
5 with false information in it. Now, is that an example of
6 perhaps an admission that regardless of what you put there, we
7 charge for the four? And then I have the slips issue, the
8 three or four, where you've got a specific instance of a
9 potential false claim, as opposed to this overarching thing,
10 like, you're forcing doctors into this tough choice.

11 MR. DeNINNO: Well, your Honor, in those situations,
12 again, the *Hutcheson* case, I think there are some other --
13 there are other cases.

14 THE COURT: Okay, I'll look. All right, so this is --
15 Yes, Mr. Gelb?

16 MR. GELB: I don't think there's enough in the
17 complaint to conclude that that was an admission. It could be
18 a statement that was made, but the corporation, it only admits
19 something if the person who says it has authority to bind the
20 company, and that's not alleged.

21 MR. DeNINNO: Your Honor, it doesn't have to be an
22 admission. These were presented as company -- the face-to-face
23 training was presented as the policy of the company to send a
24 DVD rather than provide face-to-face training.

25 THE COURT: All right, all right, all right, this is

1 what I'm going to do: As I mentioned, the overarching theory I
2 don't think I'm going to accept. There are alternative
3 theories, some of which might fly, but all discovery is stayed
4 except as to the Alere with these three or four.

5 MR. KASSOF: Two.

6 THE COURT: Two. No, no, no, whether or not you
7 submit for three strips or four strips, and only allowed with
8 respect to Mr. Allen's bills for the two years and what
9 happened. And then if I find that there's a fraud, then I'll
10 deal with whether or not it should be extrapolated, as opposed
11 to a good-faith disagreement about what a regulation provides
12 or even just a misimpression that you might have. So I think
13 that can be done pretty quickly. You can probably get him his
14 billing information in how long?

15 MR. KASSOF: We can do, as per this, your Honor,
16 within three weeks maybe? Because for sure we can do -- on the
17 two claims, we can give exactly why it is that we submitted
18 it --

19 THE COURT: No, but just this whole billing issue,
20 it's only two years, how long would it take?

21 MR. KASSOF: Three or four weeks.

22 THE COURT: So he can get the other year. And if
23 there were a bunch of them, then you might have a problem. If
24 there weren't a bunch of them, maybe -- well, if there are a
25 bunch of them, maybe there's a -- my law clerk actually looked

1 up the regulation, and it's not so clear actually -- maybe you
2 agree with that, I don't know -- on what you're supposed to do
3 if there's a bad test result. It may be an ambiguity in the
4 regulation, do you report it or not? I'll just have to make
5 whatever decision I make, but I think that's a very narrow
6 range of discovery that can happen while I write this opinion.
7 But otherwise I'm going to just have to take this under
8 advisement, and I don't think it's likely I'm going to accept
9 the overarching theory.

10 Also, my preliminary impression, which I don't intend
11 to be held to, but it's just having something on the website --
12 I may look -- it's probably going to be down by the time I get
13 into my chambers -- but, anyway, just having an old study on a
14 website without direct ties to the doctor --

15 MR. DeNINNO: Your Honor, if I may --

16 THE COURT: I'm going to assume it's the website. I
17 know you just said marketing material. I'm going to assume
18 it's what you just said.

19 MR. DeNINNO: Well, to the extent, there is additional
20 detail. The complaint pleads that as an example. It cites
21 numerous other studies. We would request the opportunity to
22 amend and provide additional --

23 THE COURT: Not right now you're not. We're going to
24 rule it, and then I'll deal with what we're dealing with. This
25 has been briefed to death. So I will take sort of the putative

1 amendment about the website, but I'm not sure that gets to the
2 doctor is the thing. The only thing that's getting directly to
3 the doctor is the thing on the form, that one company they had
4 on the form.

5 MR. DeNINNO: Well, your Honor, as long as we're
6 discussing the websites, and I'm not going to be able to
7 identify specifically which defendants have which websites, but
8 the majority, maybe all, of the defendants have specific
9 subsections of their websites that are directly targeted to
10 physicians.

11 THE COURT: It's too late now. It's just too late.
12 It's too late. We just went through the argument. It's 12:15.
13 I've just spent two and a half hours with you. I'm not going
14 to start it up again. But, in any event, it's all under
15 advisement except for the two years' worth of submitted claims
16 with respect to Mr. Allen.

17 MR. DeNINNO: Your Honor, just one more.

18 MR. KASSOF: We'll do the two years as well, but we'll
19 also, your Honor, provide the failed test information that we
20 do have for the two claims that he's identified.

21 THE COURT: Thank you.

22 MR. DeNINNO: Your Honor, I just wanted to reiterate
23 one more time, since we're talking about getting to the doctor,
24 we do plead that Roche did contact, make direct contact to
25 Buffalo Cardiology to induce Buffalo Cardiology to change their

1 patients over to the weekly testing. That's beyond just the
2 website marketing materials.

3 THE COURT: But then they didn't.

4 MR. DeNINNO: No. The complaint and Dr. Riegel's
5 affidavit says that he did start signing them for other
6 patients in addition to Mr. Allen that had previously been
7 testing pursuant to the Buffalo Cardiology --

8 THE COURT: I thought with Allen, he said he doesn't
9 need it, so they stopped.

10 MR. DeNINNO: But the complaint also -- my only point,
11 your Honor, is that we also allege that Roche contacted him
12 directly and had all of the patients who were previously tested
13 pursuant to their algorithm, which the algorithm is attached as
14 an exhibit; and if they had tested pursuant to the algorithm
15 and they had tests that were previously in range, then they
16 would be directed, pursuant to the algorithm, to test in a
17 month, not in two weeks, as Roche started requiring.

18 THE COURT: Right, right.

19 MR. DeNINNO: So those are specific --

20 THE COURT: So there's no evidence that the clinic
21 switched anyone.

22 MR. DeNINNO: But Dr. Riegel said that he signed, in
23 addition to Allen, that he signed Roche's new prescription
24 slips with regard to other patients.

25 THE COURT: But he signed them. Anyway, I get the

1 point. All right, thank you.

2 MR. PEARLSTEIN: Thank you, your Honor.

3 THE COURT: All right, thank you.

4 THE CLERK: All rise.

5 (Adjourned, 12:18 p.m.)

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C E R T I F I C A T E

UNITED STATES DISTRICT COURT)
DISTRICT OF MASSACHUSETTS) ss.
CITY OF BOSTON)

I, Lee A. Marzilli, Official Federal Court Reporter,
do hereby certify that the foregoing transcript, Pages 1
through 79 inclusive, was recorded by me stenographically at
the time and place aforesaid in Civil Action No. 16-11372-PBS,
United States of America, et al v. James F. Allen, et al, and
thereafter by me reduced to typewriting and is a true and
accurate record of the proceedings.

Dated this 7th day of May, 2018.

/s/ Lee A. Marzilli

LEE A. MARZILLI, CRR
OFFICIAL COURT REPORTER